

REMARKS

Claims 1-14 were pending in the application. Claims 1-10 were rejected. Claims 11-14 are withdrawn from consideration and claim 3 is herein cancelled. Claims 1 and 5 are amended and claim 15 is new. None of the amended or new claims introduce new subject matter. Amended claim 1 contains the limitation of cancelled claim 3. New claim 15 is the same as previous claim 5 before the current deletion to that claim.

35 U.S.C. § 102

Claims 1, 2, 4-8 and 10 and 3 were rejected under 35 U.S.C. § 102(b) as anticipated by Kulbe et al. (US 4,689,322). Applicant traverses the rejection.

The Examiner has failed to provide a prima facie showing of anticipation because the Examiner has not argued that each and every limitation of the rejected claims are shown in the prior art. The Examiner has merely argued that some of the limitations are shown in the prior art. This is not sufficient to sustain a rejection of anticipation.

With regard to former claim 3, now presented as claim 1, the Examiner has failed to find in the prior art the limitations of a hydrogel with a degree of crosslinking in the range of 30-90%. Nowhere in Kulbe does it discuss a hydrogel that is crosslinked. On page 4 of the Office Action, the Examiner stated that the composition of Kulbe is made in substantially the same way as the instantly claimed composition, so it is assumed the composition of Kulbe meets the limitations of (former) claim 3. However, it is not correct that the composition of Kulbe is made in substantially the same way as the instant composition. The present application discloses that when an aqueous 0.5 mass% sodium alginate solution is dropped into an aqueous solution of a polyvalent metal salt and the resultant solution is washed with water, the degree of crosslinking reaches 90% within one hour (page 7, lines 2-8). Therefore, in Examples 1-7 of the present application (pp. 11-14), subsequent to placing the drop of sodium alginate solution into the calcium chloride solution, the crude product is left standing at rest for less than one hour before washing with water to expel unwanted products, thus controlling that the crosslinking is less than 90%. Unlike the present invention, Kulbe matures the beads for 12 hours at 4°C to make them fully hard (Col. 14, lines 37-42). Thus, the Examiner is incorrect in stating at page 4, second paragraph that the composition of Kulbe is made in substantially the same way as the instantly

claimed invention and it is error to believe the degree of crosslinking should be assumed to be the same. Since the Examiner is relying on the theory of inherent anticipation, the Examiner is required to show that the unstated limitation would *necessarily* be known to occur in the prior art. MPEP 2112 (IV). However, as explained above, the percentage of crosslinking of the hydrogel would be called into question for the Kulbe preparation, given the differences in the method of making the prior art Kulbe composition versus the present composition.

Further, the Examiner is in error in stating that the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. The burden is initially on the Examiner to make a *prima facie* showing of anticipation. It is only after the Examiner makes a *prima facie* case that the burden shifts to the applicant. In the case of inherent anticipation, as above, the burden is first on the Examiner, as stated below:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). MPEP 2112 (IV).

For the above reason, the Examiner has failed to make a *prima facie* showing that the Kulbe composition is a hydrogel that has a degree of crosslinking in the range of 30-90%, as in claims 1-10. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

35 U.S.C. § 103

Claim 3 was rejected under 35 U.S.C. § 102(b) as anticipated by Kulbe et al. (US 4,689,322) or in the alternative under 35 U.S.C. § 103(a) as obvious over Kulbe et al. The limitations of claim 3 are now in present claim 1. Applicant traverses the rejections for all the reasons stated above.

Moreover, the Examiner has not set forth a *prima facie* showing of obviousness because the Examiner has failed to assess obviousness according to the requirements of the *Graham* analysis. *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). MPEP 706.02(j). Namely the Examiner has failed to present any reason why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. The Examiner

seems to have merely stated a reason for inherent anticipation (which was rebutted above) without providing any reason for an obviousness rejection. Because there has been no *Graham* analysis, Applicant submits that the claim(s) are patentable.

"[T]he Examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). See also MPEP 706.02(j)

Claims 1-10 were rejected under 35 U.S.C. § 103(a) as obvious over Aoyagi et al., (U.S. 6,299,867; US '867). Applicant traverses the rejection.

Claim 9 is directed to an agent for preventing and healing constipation containing a hydrogel, wherein the hydrogel contains an activated carbon in an amount in the range of 1-90 mass%. The Examiner cited US '867, and specifically col. 12, example 7 as teaching adsorbents formed by coating active carbon with calcium alginate. However, this cite merely teaches preparation of a solution of sodium alginate containing 0.3 wt.% of active carbon. Thus the cited passage does not meet the claim 9 limitation of activated carbon in the range of 1-90 mass %. Since the Examiner's reasoning provides no cure for this defect in the prior art, the claim is non-obvious and patentable over the art.

Still further, the claims have been amended so that the property of preventing and healing constipation is now recited in the body of the claim as a limitation to be considered. Not only is US '867 devoid of any teaching of an agent that prevents and heals constipation, but, to the contrary, it suggests that the adsorbent disclosed therein works in the opposite manner. First, US'867 states that: "When the active carbon is directly ingested into the digestive system as a medicinal carbon for the purpose of removing by adsorption such substances as induce autointoxication, medicinal poisoning, etc. however, it is liable to do harm by causing constipation." (Col. 1, lines 15-19). Although US'867 states that its adsorbent avoids *inducing* constipation (Col 3, lines 38-45), it does not state that it prevents and heals constipation. Rather US'867 teaches that the adsorbent is useful to prevent diarrhea, the opposite affliction (Col. 23, lines 18-48).

It is clear from the above, that US'867 does not teach any substance that prevents and heals constipation. As such, and in light of its teachings to the contrary, one of ordinary skill in the art would have had no reason to expect a successful outcome in using an adsorbent which is active carbon coated with a hydrogel of a polyvalent metal salt of alginic acid for the purpose of preventing and healing constipation. For this reason, the claims are not obvious over the US'867 prior art.

Applicant respectfully requests that the obviousness rejections be reconsidered and withdrawn.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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